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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/027,267	12/21/2001	Dennis Stein Everhart	16,540	3116
23556	7590	06/16/2004	EXAMINER	
KIMBERLY-CLARK WORLDWIDE, INC.			STEPHENS, JACQUELINE F	
401 NORTH LAKE STREET			ART UNIT	
NEENAH, WI 54956			PAPER NUMBER	
			3761	

DATE MAILED: 06/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/027,267

Applicant(s)

EVERHART ET AL.

Examiner

Jacqueline F Stephens

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-63 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,12,16,18,21,22,33-43,45,47-52,54,55,59,62 and 63 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)       |
| Paper No(s)/Mail Date <u>3/19/04, 2/14/03</u>  | 6) <input checked="" type="checkbox"/> Other: <u>IDS 1/27/03, 9/18/02, 9/3/02</u> |

**Continuation of Disposition of Claims: Claims withdrawn from consideration are 2,4-11,13-15,17,19,20,23-32,44,46,53,56-58,60 and 61.**

**DETAILED ACTION**

***Election/Restrictions***

1. Applicant's election without traverse of claims 1, 3, 12, 16, 18, 21, 22, 33-41, 42, 43, 45, 47-52, 54, 55, 59, 62, and 63 in the reply filed on 4/27/04 is acknowledged.

***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 12, 16, 21, 34, 35, 42, 47, and 63 are rejected under 35 U.S.C. 102(b) as being anticipated by Lucas AU 199941153.

As to claims 1 and 42, Lucas discloses a tampon and method for producing a tampon comprising a fluid-absorbent body and a therapeutic agent located within an application region of the tampon (page 3, lines 18-23 and Figures 1 and 2).

As to claims 12 and 16, Lucas discloses the therapeutic agent is a powder, which is also a solid (page 2, lines 12-14).

As to claim 21, Lucas discloses the therapeutic agent is capable of treating dysmenorrhea (page 4, lines 7-10).

As to claims 34 and 47, Lucas discloses the therapeutic agent is applied to the surface of the tampon body (page 3, lines 18-23 and Figures 1 and 2).

As to claim 35, Lucas discloses the therapeutic agent is applied to the surface of the tampon body. The limitation of the agent being applied before the body is constructed is directed to a process of making the article. "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted). MPEP 2113.

As to claim 63, Lucas discloses a tampon and method for producing a tampon comprising a fluid-absorbent body and a therapeutic agent located within an application region of the tampon (page 3, lines 18-23; page 4, lines 4-5; and Figures 1 and 2).

4. Claims 1, 21, 22, 39, 40, 42, 43, 55, and 62 are rejected under 35 U.S.C. 102(b) as being anticipated by Harrison et al. USPN 6086909.

As to claims 1, 42, and 55, Harrison discloses a tampon and method for producing a tampon comprising a fluid-absorbent body 24 and a therapeutic agent 28 located within an application region of the tampon (Figure 4).

As to claims 21, 39, and 40, see Abstract and col. 13, lines 34-60.

As to claim 22, Harrison discloses the claimed therapeutic agents (col. 4, lines 43-59).

As to claims 43 and 62, Harrison discloses a mucoadhesive (col. 2, lines 60-63).

5. Claims 1, 3, 16, 18, 36-39, 41, 42, 45, 48-51, 52, 55, and 59 are rejected under 35 U.S.C. 102(b) as being anticipated by Goldfarb et al. USPN 3490454.

As to claims 1, 3, 18, 38, 42, 45, 51, 52, and 55, Goldfarb discloses a catamenial product and method for producing the product, which is capable of being partially positioned within the vestibule of a wearer and contacting the non-cornified epithelium. Goldfarb discloses a tampon product col. 2, lines comprising a fluid-absorbent body and means for carrying a formulation including a therapeutic agent (col. 2, lines 16-21; col. 3, lines 4-10; col. 4, lines 8-14).

As to claims 36 and 49, Goldfarb discloses the agent is located on an open or a gauze nonwoven, either of which is essentially an apertured web (col. 3, lines 53-54 and col. 4, lines 8-14).

As to claim 37, Goldfarb discloses the therapeutic agent is applied to creped tissue, which is well known in the art as a biodegradable material (col. 3, lines 34-44).

As to claim 39, Goldfarb discloses the therapeutic agent comprises a hydrogel (col. 6, lines 45-75).

As to claim 41, Goldfarb discloses the therapeutic agent comprises a polymeric material (col. 8, lines 8-38).

As to claims 48 and 50, Goldfarb discloses the agent is applied to various layers and between layers of the absorbent product (col. 3, lines 34-44 and col. 4, lines 8-10). Therefore, the agent is applied before the body is completed.

As to claim 59, Goldfarb discloses delivery of the therapeutic agent is affected by melting a solid (col. 7, lines 1-8).

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lucas in view of Bowie et al. USPN 5585277. Lucas discloses the present invention substantially as claimed. However, Lucas does not disclose a ligand as part of the formulation. Bowie discloses ligands can be used therapeutically to bind a target

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protein associated with a condition or disease, preventing or treating a condition or disease, regulate physiological function, or serve as a lead compound for identification of a therapeutically useful compound (col. 1, lines 51-60). It would have been obvious to one having ordinary skill in the art to modify the therapeutic agent of Lucas with a ligand for the benefits disclosed in Bowie.

9. Claim 54 is rejected under 35 U.S.C. 103(a) as being unpatentable over Goldfarb USPN 3490454 in view of Karami et al. USPN 4726976.

As to claim 54, Goldfarb discloses a catamenial product and method for producing the product, which is capable of being partially positioned within the vestibule of a wearer (Goldfarb discloses a tampon product col. 2, lines comprising a fluid-absorbent body and means for carrying a formulation including a therapeutic agent (col. 2, lines 16-21; col. 3, lines 4-10; col. 4, lines 8-14). Goldfarb discloses the agent is located on a porous nonwoven (col. 3, lines 53-54 and col. 4, lines 8-14). However, Goldfarb does not disclose the nonwoven is a hydrophobic polymer. Karami discloses a hydrophobic coversheet for the benefit of reducing rewet (col. 6, lines 33-53). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Goldfarb with a hydrophobic cover layer for the benefits disclosed in Karami.



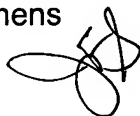
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacqueline F Stephens whose telephone number is (703) 308-8320. The examiner can normally be reached on Monday-Friday 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Calvert can be reached on (703) 305-1025. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jacqueline F Stephens  
Examiner  
Art Unit 3761



June 14, 2004